DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

May 15, 2015

Cynosure, Inc.
% Kevin O' Connell
Director Regulatory Affairs
5 Carlisle Road
Westford, Massachusetts 01886

Re: K150230
Trade/Device Name: SculpSure
Regulation Number: 21 CFR 878.5400
Regulation Name: Low Level Laser System for Aesthetic Use
Regulatory Class: Class II
Product Code: PKT
Dated: January 30, 2015
Received: February 4, 2015

Dear Mr. O' Connell,

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in

the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Jennifer R. Stevenson -S

For Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K150230

Device Name
Cynosure SculpSure

Indications for Use *(Describe)*
Indications for use: The Cynosure SculpSure is intended for non-invasive lipolysis of the flanks to achieve disruption of adipocyte cells intended for non-invasive aesthetic use to achieve a desired aesthetic affect. Intended for individuals with a Body Mass Index (BMI) of 30 or less.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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510(k) SUMMARY

A summary of 510(k) safety and effectiveness information in accordance with the requirements of 21 CFR 807.92.

807.92(a)(1) - Submitter Information	
Name	Cynosure, Inc.
Address	5 Carlisle Road Westford, MA 01886 USA
Phone number	978-367-8736
Fax number	978-256-6556
Establishment Registration Number	1222993
Name of contact person	Kevin J. O'Connell
Date prepared	May 14, 2015
807.92(a)(2) - Name of device	
Trade or proprietary name	SculpSure™
Common or usual name	Laser
Classification name	Laser for disruption of adipocyte cells for aesthetic use
Classification panel	General and Plastic Surgery
Regulation	21 CFR 878.5400
Product Code(s)	PKT
807.92(a)(3) - Legally marketed device(s) to which equivalence is claimed	
	Zeltiq Coolsculpting Device K133212 Cynosure Smartlipo MPX Laser K083795 Cynosure 1064 nm Diode Laser K123971
807.92(a)(4) - Device description	
	The Cynosure SculpSure is a diode laser system. Electrically efficient semiconductors generate optical radiation (1064 nm) which is used to directly irradiate the skin's surface. The Sculpsure is intended for non-invasive lipolysis of the flanks to achieve disruption of adipocyte cells intended for non-invasive aesthetic use to achieve a desired aesthetic affect. The main components of SculpSure are a console and applicator.
807.92(a)(5) Intended use of the device	
Indications for use	The Cynosure SculpSure is intended for non-invasive lipolysis of the flanks to achieve disruption of adipocyte cells intended for non-invasive aesthetic use to achieve a desired aesthetic affect. Intended for individuals with a Body Mass Index (BMI) of 30 or less.

807.92(a)(6) Summary of the technological characteristics of the device compared to the predicate				
Characteristic	SculpSure	Zeltiq Coolsculpting Device K133212	Cynosure Smartlipo MPX Laser K083795	Cynosure 1064 nm Diode Laser K123971
Lipolysis Method	heat – assisted	cold – assisted	heat – assisted	n/a
Laser Type	Diode	N/A	Nd:YAG	Diode
Wavelength	1064 nm	n/a	1064 nm	1064 nm
Power Density	1.7 W/cm^2	n/a	n/a	5 W/ cm^2
Power Modes	Continuous with duty cycle			Continuous, Pulse Modulation
Pulse Length	1s to 20 s	n/a	0.1 – 300 ms	100ms – 500ms
Applicator size	4 x 6 cm^2 (3X)	4.5 x 7 cm^2 (2x) approximate	300,600,1000 µm	3 x 10 cm^2
Attachment to patient	Belt	belt	n/a – fiber is manipulated by operator	belt

807.92(b)(1) NONCLINICAL TESTS SUBMITTED	
Discussion of nonclinical tests:	Software verification and validation was performed, and demonstrated that the software performs as intended. Electromagnetic compatibility and electrical safety testing was performed per standards IEC 60601-1, IEC 60601-1-2, IEC 60825-1 and IEC. Results confirmed the device met the standards.

807.92(b)(2) CLINICAL TESTS SUBMITTED	
Discussion of Clinical Study:	A preliminary study was performed to demonstrate the use of hyperthermic treatment to cause the same type of injury to adipocytes as hypothermic treatment (predicate). It was concluded that histologic, quantitative measurements, as well as aesthetic level of improvement show comparable results between hyperthermic and hypothermic treatment of adipocytes resulting in fat reduction. Pre-clinical testing was performed to demonstrate that the device would elevate the temperature of the tissue to 42 – 47 °C. The clinical study was performed at two centers using 49 subjects ages 25 – 61 with unwanted fat in the flanks. Racial demographics of the subjects included: Caucasian, African American, Hispanic, Indian and Asian. The BMI of the subjects ranged from 21.6 to 35. Subjects include all Fitzpatrick skin types (I – VI). 42 of the subjects were female and 7 were male.

	The primary endpoint was photographic evaluations with correct identification of pre-treatment images compared to post treatment images. Secondary endpoint was a change from baseline in adipose layer thickness between device and control based on ultrasound measurements. The third endpoint was subject satisfaction survey. Before treatment each subject was photographed, ultrasound images taken and weight recorded. Each subject received one treatment with the device. Post treatment follow up was at 1 week (optional), 6 weeks and 12 weeks. Before and after (12 week post treatment) photographs of the 43 of 49 subjects that returned were evaluated individually by three blinded evaluators. In 88% of the total individual evaluations the evaluators correctly identified the before and after images. The blinded evaluators were board certified dermatologists. There was an average of 13% normalized fat reduction based on ultrasound measurements at 12 weeks. Ninety eight percent of the patients rated the treatment satisfied on the Likert Satisfaction scale. Therefore all endpoints were met. Patients were evaluated for adverse events immediately after treatment and at all follow up visits. There were no deaths, serious adverse events (SAEs) or unanticipated adverse device effects (UADEs) reported in this study. The events that were logged were typical reactions to laser treatments including edema, bruising, pain, blistering, and erythema; nodule and hardness due to inflammation. All events transient and resolved without medical intervention.
807.92(b)(3) Conclusion	
Nonclinical testing performed confirmed that the device met its specifications. Clinical testing performed confirmed that the device achieved disruption of adipocyte cells which achieved a desired aesthetic affect without any serious adverse events or unanticipated adverse device effects	